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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,131	07/30/2003	George A. Lopez	ICUMM.011C8C5	9000
20995	7590	02/25/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			THANH, LOAN H	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



<p align="center"><b>Office Action Summary</b></p>	<b>Application No.</b> 10/630,131	<b>Applicant(s)</b> LOPEZ, GEORGE A.	
	<b>Examiner</b> LoAn H. Thanh	<b>Art Unit</b> 3763	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-119 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-119 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>06/30/04, 07/30/03</u> . | 6) <input type="checkbox"/> Other: _____  |



## DETAILED ACTION

### *Information Disclosure Statement*

The information disclosure statement filed 07/30/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of **each non-patent literature publication** or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Applicant is requested to make these articles of record for the Examiner to consider.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-34, 61-63, 93-94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32, 61, 93 recites the limitation "the orifice" in line 1. There is insufficient antecedent basis for this limitation in the claim.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –



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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-34,38-41,44-45,48-56, 85-101, 103-105, 108-119 are rejected under 35 U.S.C. 102(b) as being anticipated by Vaillancourt ( USPN 4,998,927).

Vaillancourt discloses in figures 3-4 a valve device comprising a housing, with a first and second horizontal cross section wherein the second cross sectional width is larger than the first cross-sectional width, a flexible element disposed within the internal cavity of the housing having a first and second height wherein the first height is greater than the second height and a spike element 44. Further, Vaillancourt discloses a skirt and thread section in the distal portion of the housing.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 35-37,42-43,46-48,57-84, 102,106-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaillancourt ( USPN 4,998,927).

Vaillancourt discloses the invention as substantially claimed.

With respect to claims 35-37, Vaillancourt does not disclose a third cross section width. Lacking any criticality in the design choice of a third horizontal cross section width larger than the second cross sectional width, Examiner is taking the position that



matters relating to ornamentation only, which have no mechanical function, cannot be relied upon to patentably distinguish the claimed invention from the prior art. The particular shape of a product is of no patentable significance since it appears to be a matter of choice that a person of ordinary skill in the art would find obvious absent persuasive evidence that the particular configuration of the claimed container was significant. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

With respect to claims 42-43, 57-84, 102, Vaillancourt is silent to the spike being formed of plastic. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the material of the spike to suit the area to which it would be applied to, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended uses as a matter of obvious engineering choice lacking any criticality. In re Leshin, 125 USPQ 416.

With respect to claims 46-47, 74-75, 106-107, Vaillancourt discloses the spike a certain distance from the proximal end of the housing. However, Vaillancourt is silent to the spike being positioned approximately 0.1" to 0.525" from the proximal end of the housing. Lacking any criticality in the specific range of the distance, the prior art would perform equally well since there is also a distance that the spike needs to be a distance from the proximal end of the housing in order to allow the valve to be activated upon application of a medical instrument to puncture and allow fluid flow therein. It would have been obvious to one of ordinary skill in the art at the time the invention was made



to modify the distance as determined by the length of the needle to pierce the septum in order to allow fluid to flow through the valve.

**Remarks**

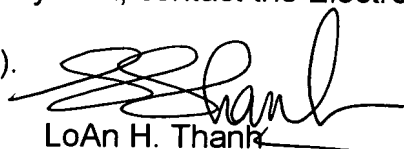
In the event that applicant is shows that the filing date accorded should be earlier the 102(b) rejection would be applied as a 102(e) rejection.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LoAn H. Thanh  
Primary Examiner  
Art Unit 3763